UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte JONATHAN L. MILLER and VICKI A LYLE

Appeal No. 2005-0226
Application No. 09/258,947

ON BRIEF

Before ELLIS, ADAMS, and MILLS, Administrative Patent Judges.

ADAMS, Administrative Patent Judge.

VACATUR and REMAND TO THE EXAMINER

On consideration of the record we find this case is not in condition for a decision on appeal. For the reasons that follow, we vacate[1] the pending rejection under 35 U.S.C. § 112, first paragraph and remand the application to the examiner to consider the following issues and to take appropriate action.

[1] Lest there be any misunderstanding, the term "vacate" in this context means to set aside or to void. When the Board vacates an examiner's rejection, the rejection is set aside and no longer exists.

Claims 9 and 11 are the only pending claims in the application. Claim 9 is illustrative of the subject matter on appeal and is reproduced below:

> 9. An isolated peptide of 5 to 20 or 20 to 40 amino acid residues in length capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO:174, wherein the isolated peptide inhibits ristocetin induced aggregation of platelets, and wherein the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide.

No prior art is relied upon by the examiner.

GROUNDS OF REJECTION

Claims 9 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as the specification that fails to adequately describe the claimed invention.

Claims 9 and 11 stand rejected under 35 U.S.C. § 112, first paragraph, as being based on an insufficient disclosure to support or enable the scope of the claimed invention.

DISCUSSION

According to appellants' (specification, page 1), "[t]he present invention relates to a peptide capable of functionally mimicking the binding site for a monoclonal antibody (i.e. a mimotope), ... and to isolated molecules capable of binding to the peptide (i.e. an anti-mimotope). At page 5 of the specification, appellants disclose,

> [t]he invention thus provides an isolated peptide that functionally mimics a binding site for a monoclonal antibody, the monoclonal antibody recognizing an epitope within the human platelet glycoprotein Ib/IX complex. This isolated peptide is a mimotope. A peptide functionally mimics a binding site for a monoclonal antibody if the monoclonal antibody can bind to the peptide. Preferably, the

> isolated peptide [(the mimotope)] comprises an amino acid sequence as shown in SEQ ID NO:174: WRXXEY.
>
> ...
>
> Preferably, the isolated molecule [(the anti-mimotope)] is capable of binding to the isolated peptide described above (the isolated peptide that comprises an amino acid sequence as shown in SEQ ID NO:174). This preferred isolated molecule [(the anti-mimotope)] inhibits ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide [(the mimotope)].

Appellants disclose, that the mimotope peptide represented by SEQ ID NO:174 mimics the binding site for a monoclonal antibody (e.g. monoclonal antibody C-34). Specification, page 11. Stated differently monoclonal antibody C-34 binds to the peptide mimotope having SEQ ID NO:174. According to appellants (specification, page 17), "[t]he invention also provides an isolated molecule [(an anti-mimotope)] capable of binding to the [mimotope] peptide [(e.g. the peptide represented by SEQ ID NO:174)]." Specification, page 17. In this regard, appellants provide the sequence for a number of anti-miotope peptides, including SEQ ID NO:94. See specification, pages 17-18. In summary, appellants disclose (specification, page 22),

> [p]referably, the anti-mimotope is an isolated molecule capable of binding to an isolated peptide, wherein the isolated peptide comprises an amino acid sequence as shown in SEQ ID NO:174. This isolated molecule inhibits ristocetin induced aggregation of platelets and has a three dimensional structure complementary to the three dimensional structure of the isolated peptide (comprising an amino acid sequence as shown in SEQ ID NO:174). The concept of "complementary" is illustrated in Fig. 12a-12c.

Figures 12a-12c provide a 2-dimensional illustration of what appellants call the "concept of complementary." With reference to figures 12a-12c appellants disclose (specification, page 46), "[t]he anti-mimotope peptide [(labeled "14" in figure 12c)] sequence is complementary to the face of the mimotope peptide [(labeled "12" in figure 12b and 12c)] in three-dimensional space, as monoclonal antibody C-34 was to the original epitope [(labeled "10" in figure 12a)]...."

Against the foregoing backdrop we consider appellants' claimed invention. To avoid confusion we limit our discussion to claim 9. As we understand it, the peptide of claim 9 is capable of binding a second peptide having SEQ ID NO:174. As discussed above, the peptide having SEQ ID NO:174 is a mimotope, therefore, when read in light of appellants' specification the peptide of claim 9 appears to be an anti-mimotope. Claim 9 requires that the claimed peptide must have two structural properties and two functional properties. Structurally, the claimed peptide must:

1. be 5 to 20 or 20 to 40 amino acid residues in length; and

2. have a three dimensional structure complementary to the three dimensional structure of a second peptide having an amino acid sequence as shown in SEQ ID NO: 174.

Functionally, the claimed peptide must:

1. be capable of binding to a second peptide having an amino acid sequence as shown in SEQ ID NO: 174; and

2. inhibit ristocetin induced aggregation of platelets.

The examiner has rejected appellants' claimed invention under both the written description provision and the enablement provision of 35 U.S.C. § 112, first paragraph. Under the written description provision the examiner found that appellants' specification provided an adequate written description of only one peptide falling within the scope of the claimed invention, specifically the peptide having SEQ ID NO:94. Answer, pages 3-4. Similarly, under the enablement provision, the examiner found that appellants' specification provided an enabling disclosure of only one peptide falling within the scope of the claimed invention, specifically the peptide having SEQ ID NO:94. Answer, pages 4-5. According to the examiner (Answer, page 6),

> as shown in Figure 8 and disclosed at page 42, lines 29-32, the other disclosed peptides which bind the peptide of SEQ ID NO:174 fail to inhibit ristocetin induced platelet aggregation. Also note that none of the peptides are shown to have three dimensional structure complementary to the three dimensional structure of the peptide of SEQ ID NO:174.

Regarding the limitation in claim 9 that the claimed peptide "has a three dimensional structure complementary to the three dimensional structure of the" peptide having SEQ ID NO:174, the examiner emphasizes (Answer, page 7), "no species meeting said limitation are disclosed, nor is it even disclosed how the skilled artisan would establish whether or not the limitation had been met." In addition, we note the examiner's assertion (Answer, page 8), "regarding the 'complementary three dimensional

structure' of [c]laim 9, it has not been established that even the peptide encoded by SEQ ID NO:94 meets that limitation."

For the following reasons it is our opinion that the examiner's analysis is inconsistent with the finding that the specification provides an adequate written description and an enabling disclosure of an isolated peptide having SEQ ID NO:94. In addition, notwithstanding the examiner's finding to the contrary, it appears that the specification discloses several peptides that exhibit the ability to inhibit ristocetin-induced aggregation. Accordingly, we vacate the pending rejections and remand the application to the examiner for further consideration.

As set forth in In re Moore, 439 F.2d 1232, 1235, 169 USPQ 236, 238 (CCPA 1971), before issues related to the patentability of the claimed subject matter can begin to be considered, the examiner must determine what is being claimed:

> [T]he claims must be analyzed first in order to determine exactly what subject matter they encompass. . . .
>
> The first inquiry therefore is merely to determine whether the claims do, in fact, set out and circumscribe a particular area with a reasonable degree of precision and particularity. It is here where the definiteness of the language employed must be analyzed – not in a vacuum, but always in light of the teachings of the prior art and of the particular application disclosure as it would be interpreted by one possessing the ordinary level of skill in the pertinent art.

Stated differently, "speculation as to meaning of the terms employed and assumptions as to the scope of such claims" is legal error. In re Steele,

305 F.2d 859, 862, 134 USPQ 292, 295 (CCPA 1962). Accordingly, we encourage the examiner to clarify the following issues in the next Office Action.

I. Do other disclosed peptides inhibit ristocetin-induced aggregation?

With reference to Figure 8, and page 42, lines 29-32 of appellants' specification, the examiner finds (Answer, page 6), but for SEQ ID NO:94, "the other disclosed peptides which bind the peptide of SEQ ID NO:174 fail to inhibit ristocetin induced platelet aggregation." Page 42, lines 28-33 of appellants' specification discloses, "[a]s shown in Fig. 8, one single clone of 46 bacteriophage clones purified and sequentially tested demonstrated inhibitory activity above background level in a functional platelet assay. This 'anti-mimotope' clone displayed the sequence having SEQ ID NO:94...."

The examiner recognizes (see e.g., Answer, page 4), however, that appellants' specification (page 45) discloses several other peptides that exhibit the ability to inhibit ristocetin-induced aggregation of platelets. Specifically, the peptides having SEQ ID NOs: 104-108. While these peptides exhibit inhibitory activity that vary from that of the peptide having SEQ ID NO:94, we find nothing in the claims that require any specific amount of inhibition, at any specific

concentration of peptide.[2] Furthermore, the examiner offers no explanation as to why these peptides do not meet the claim requirement that "the isolated peptide inhibits ristocetin induced aggregation of platelets...."

Accordingly, we encourage the examiner to take a step back and reconsider the administrative file together with any relevant prior art to determine whether the term "inhibits" has a clear and definite meaning on this record. If the examiner finds that the term is definite, the examiner should clearly and articulately address the scope of the term on the record. Only then should the examiner address the other requirements for patentability. In the event the examiner should find the term indefinite, the examiner should clearly and articulately explain any perceived deficiency in an appropriate Office Action. In this regard, we remind the examiner, as set forth in Amgen Inc. v. Chugai Pharmaceutical Co., Ltd., 927 F.2d 1200, 1217, 18 USPQ2d 1016, 1030 (Fed. Cir. 1991):

> The statute requires that "[t]he specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." A decision as to whether a claim is invalid under this provision requires a determination whether those skilled in the art would understand what is claimed. See Shatterproof Glass Corp. v. Libbey-Owens Ford Co., 758 F.2d 613, 624, 225 USPQ 634, 641 (Fed. Cir. 1985) (Claims must "reasonably apprise those skilled in

[2] We note for example, that page 45 of appellants' specification discloses that at 200-400 µg/ml a peptide having SEQ ID NO:104 exhibited the ability to inhibit ristocetin-induced aggregation that was "slightly lower" than the peptide having SEQ ID NO:94, but at a concentration of 715 µg/ml the peptide having SEQ ID NO:104 exhibited "nearly full inhibition."

the art" as to their scope and be "as precise as the subject matter permits.").

II. A complementary three-dimensional structure:

According to the examiner (Answer, page 6), while the specification discloses a number of peptides, "none of the peptides are shown to have [a] three dimensional structure [that is] complementary to the three dimensional structure of the peptide of SEQ ID NO:174." The examiner, however, failed to identify the scope of the quoted phrase on this record.

Accordingly, we encourage the examiner to take a step back and reconsider the administrative file together with any relevant prior art to determine whether the phrase "the isolated peptide has a three dimensional structure complementary to the three dimensional structure of the second peptide" has a clear and definite meaning on this record. In particular, we encourage the examiner to consider page 46 of appellants' specification together with appellants' Figures 12a-12c.

If the examiner finds that the phrase is definite, the examiner should clearly and articulately address the scope of the phrase on the record. Only then should the examiner address the other requirements for patentability. In the event the examiner should find the phrase indefinite, the examiner should clearly and articulately explain any perceived deficiency in an appropriate Office Action.

III. Peptides having SEQ ID NOs:94-99 and 157-172:

According to appellants (Brief, page 4), "a large number of species are listed that define the claimed genus (see specification, page 17, line 23-page 18, line 15)." Upon review of the cited section of the specification we note that appellants disclose a number of "anti-mimotope [peptides] of the subject invention." In this regard, we note the examiner has neither addressed appellants' assertion that these peptides are within the scope of the claimed invention, nor has the examiner provided substantial evidence to establish that these peptides would not function as claimed.

As set forth in In re Wright, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993).

> "When rejecting a claim under the enablement requirement of section 112, the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application; this includes, of course, providing sufficient reasons for doubting any assertions in the specification as to the scope of enablement."

Accordingly, if after having the opportunity to reconsider the claimed invention in light of the administrative file and relevant prior art, the examiner believes that a rejection under 35 U.S.C. 112, first paragraph should be entered into the record, we encourage the examiner to ensure that there is sufficient evidence on the record to support such a rejection.

Any further communication from the examiner that contains a rejection of the claims should provide appellants with a full and fair opportunity to respond.

VACATED and REMANDED

Joan Ellis
Administrative Patent Judge)
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) BOARD OF PATENT
)
Donald E. Adams) APPEALS AND
Administrative Patent Judge)
) INTERFERENCES
)
Demetra J. Mills)
Administrative Patent Judge)

ROGALSKY & WEYAND, LLP
P.O. BOX 44
LIVONIA NY 14487